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March 17, 2003

United States Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Mr. Stuart Shapiro
Docket No. 02N-0278

Prior Notice of Arrival of Food Articles – Published Regulations

Dear Mr. Shapiro:

This letter responds to the proposed regulation published in the *Federal Register* of February 3, 2003 that would require the filing of a Prior Notice of every arriving food article, whether or not intended for U.S. consumption.

At the outset, we applaud the FDA's efforts to draft regulations addressing the tremendous role Congress assigned to the Agency as part of the Bioterrorism Preparedness Act of 2002. The need for proactive border enforcement is critical to protecting U.S. consumers from unsafe food articles and we fully support the FDA's mission, commitment and objectives in that regard. However, we are concerned that the regulations, as published, would increase the costs and burdens of importing food articles into this country so exponentially that the entire industry is threatened. Because we are certain that this is not the result the Agency intended, we respectfully submit to you the following thoughts and comments in connection therewith.

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BACKGROUND INFORMATION

Flegenhimer International, Inc. is a small Customs Broker company in Los Angeles. We prepare and submit entry documentation for a variety of food importers and, in particular, on behalf of domestic importers of perishable fish items from throughout the World. As we are sure you are aware, under current regulations, U.S. Customs, FDA and USDA require documentation to be filed in connection with seafood importations. In this regard, we utilize the existing AMS Customs System that allows electronic submission of all of the information required by each agency to be filed simultaneously. Without such coordinated timely, accurate and complete submission of this documentation, the perishable items would be unacceptably delayed at the Port of Entry and, frankly, we would be out of business.

ADDITIONAL DISCUSSION

The proposed Prior Notice regulations most importantly do not interface with any other agency's databases or reporting modules. In addition to the burden this will place on Customs brokers charged with ensuring proper and timely submission of import documents, this additional work will necessarily result in additional importing fees that will naturally be handed down to the importers themselves and ultimately the consuming public.

Moreover, the information required to be provided on the Prior Notice will be difficult, if not impossible, to obtain - much less verify as to accuracy. We often do not learn of the exact amount or type of fish loaded onto an aircraft or vessel until the hour before it arrives. As a result, we are unable to learn the necessary supply chain information required on the Prior Notice -- as proposed in the regulations -- so that even a simple amendment to the original Prior Notice may not be sufficient to correct the natural deficiencies. Accordingly, the original Prior Notice will have to be cancelled and a new one filed...while these perishable articles linger at the Port. In addition, we often do not learn the time of anticipated arrival of a shipment until it actually arrives --- transporters are often delayed through no fault of planning or intention and, accordingly, lack of a timely update similarly would be the result not of intentional non-compliance but unfortunate circumstance. Nevertheless, once again, the perishable goods will be left at port while a new Prior Notice is submitted, accepted and reviewed as to accuracy. Again, this duplicative work will necessarily increase the costs and burden placed upon legitimate tax-paying U.S. importers and such an extreme disruption in normal trade cannot be an acceptable consequence of these regulations.

Finally, although the underlying legislation motivating the rulemaking, i.e., the BioTerrorism Preparedness Act of 2002, requires that the FDA increase communication and information sharing between agencies, the proposed rule specifically requires no such communication or sharing of information. The information that is required to be submitted pursuant to the BioTerrorism Preparedness Act of 2002 is already being reported to U.S. Customs on a per shipment basis and there is no rationale for requiring the increased, detailed information per line item as the published rules propose. The

resulting costs for new software systems, programming operators and business operations that will be required to track the multitude of information required by the Prior Notice for each and every line item included in a single shipment is unduly burdensome and cost prohibitive.

CONCLUSION

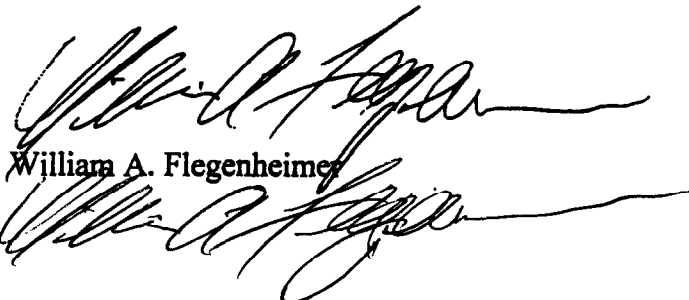
This country is largely supported by small businesses such as mine. We provide a valuable service to the importing community because we are able to ensure the safe and timely entry of perishable food items. The proposed Prior Notice regulations, however, will raise the cost of importing products into this country and will necessarily delay entry of these products so that American consumers will have no option but to forego fresh seafood entirely in favor of, perhaps, only frozen goods. This is not only unfortunate, but unnecessary.

We urge the FDA to continue its commitment to keep America's borders safe and honor its obligations under the BioTerrorism Preparedness Act of 2002 by working with the other Agencies responsible for imports into this country. Especially at this time in our country's history, when our country's importers have already evidenced their commitment to safety and integrity of imported goods by reinventing their business operations in order to comply with increased disclosure requirements established by U.S. Customs, it would be illogical for the FDA to intentionally sacrifice these same tax-paying U.S. small businesses --- providing products desired and called for throughout the domestic marketplace --- by implementing regulations that will impossible to comply with. Unfortunately, however, because of the increased costs and burdens associated with the proposed Prior Notice regulations, as published on February 3, 2003, the legitimate importing community of perishable food items in particular will suffer tremendously and may, in fact, be eliminated entirely.

Accordingly, we urge the FDA to reconsider its regulations and to particularly consider how its obligations under the BioTerrorism Preparedness Act of 2002 may be fully met by coordinating directly and sharing information with U.S. Customs and other federal agencies.

If you should have any further questions or wish to discuss this matter in greater detail, please feel free to contact the undersigned directly at any time.

Respectfully submitted,



William A. Flegenheimer